

**K012292 HUMAN IGG SUBCLASS LIQUID REAGENT KITS,  
PRODUCT CODE LK001.TB**Aug 31, 2001  
42 days to decisionK012292 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k012292/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Jul 20, 2001
Decision date	Aug 31, 2001
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>The Binding Site, Ltd.</b>
Location	Los Angeles, CA, US
Contact	JAY H GELLER
510(k) history	115 submissions · 115 cleared · 1988-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012292/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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